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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,978	01/22/2004	David Hung	12.024011	5996

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/762,978	HUNG ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *90-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2004 and 29 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 90-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 62-65 and 68 of U.S. Patent No. 6,689,070 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the current application and the issued patent both disclose a method for lavaging a human breast duct, including essentially the same structural elements and method steps. While the issued patent broadly discloses the use of a catheter with an internal lumen, the current application discloses all of the structural elements of the catheter. One of ordinary skill in the art would be able to determine a catheter would inherently have a proximal end and a distal end and have an internal lumen with a distal opening for receiving and/or delivering a fluid into the body. Furthermore, the issued patent broadly discloses an infusion device and a

collection device, while the current claims disclose a syringe for infusing a fluid and a syringe for collecting the fluid. One of ordinary skill in the art would be able to determine that an infusion device would inherently be a syringe, while the collection device would also inherently be a syringe. Since the claims of the issued patent broadly disclose the limitations of the current claims of the application, the current claims are not patentably distinct from the issued claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 90-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cecchi (5,843,023) in view of Hou et al (A Simple Method of Duct Cannulation and Localization for Galactography before Excision in Patients with Nipple Discharge).

Cecchi discloses an aspiration needle with a side port and further disclose: a manifold hub (17) in fluid communication with the cannula (13), the manifold hub (17) comprising a distal end having a first port (29) for infusing fluids into the hub (17) and a second port (16) for collecting fluid from within the hub (17); infusing a lavage fluid through the first port (29) and into the hub (17) (See Figures 1 and 2; and Column 5, lines 21-24); infusing lavage fluid from the hub (17) into the target site through the internal lumen (30) of the cannula (13) (See Figures 1 and 2; and Column 5, lines 21-

24); withdrawing the lavage fluid and substances borne by the lavage fluid from the target site through the lumen (30) of the cannula (13) and into the hub (17); delivering the lavage fluid into a collection device (26) through the second port (16) of the hub (17) (See Column 3, lines 9-14; and Column 5, lines 21-24); infusing the lavage fluid includes the step of applying a positive infusion pressure within the internal lumen (30) (See Column 3, lines 11-14; and Column 5, lines 22-24); the positive pressure is applied by a syringe (See Column 5, lines 22-24; "injecting saline or other media" inherently discloses the use of a syringe); infusing the lavage fluid includes applying a positive pressure within the hub (17) (See Column 5, lines 22-24); withdrawing the lavage fluid and substances includes applying negative pressure within the internal lumen (30) (See Column 5, lines 22-23 and 46-47); the negative pressure is applied by a collection device, which is a syringe (See Column 5, lines 46-47); and withdrawing the lavage fluid and substances includes applying a negative pressure within the hub (17) (See Column 2, lines 62-64; the vacuum source creates a vacuum which is then transmitted to the hub and then to the internal lumen of the cannula in order to aspirate the sample).

Cecchi however fail to disclose inserting a distal end of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct.

Hou et al disclose a method and means for placing a lavage fluid within a breast duct and receiving fluid from within the duct, and further disclose inserting a distal end

of a catheter through the ductal orifice and into a distal lumen of a duct or ductal network; the catheter comprising a proximal end and a distal end, and an internal lumen extending between the proximal and distal ends, the distal end including an opening for delivering lavage fluid within the duct and receiving fluid from within the duct. See Paragraph 4, under Materials and Methods, page 568, lines 1-7 and 12-17.

Since both Cecchi and Hou et al disclose means for infusing a lavage fluid and aspirating the lavage fluid and biological material from a target site, it would have been obvious to one of ordinary skill in the art to modify the method of Cecchi to utilize the device for lavaging a breast duct, as per the teachings of Hou et al, since it would provide a means of utilizing a first syringe for creating a vacuum and aspirating a fluid sample from the biopsy site and a second syringe for providing a lavage fluid to the biopsy site.

Response to Arguments

5. Applicant's arguments filed January 29, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Cecchi fails to teach or suggest a method of lavaging a breast duct. The Examiner, in the previous rejection, did not disclose that Cecchi teaches or suggests a method of lavaging a breast duct, and agrees with the Applicants that Cecchi does not teach this method. However, Cecchi does clearly teach and suggest a means of lavaging an ovary to obtain an oocyte. The same elements can be

used to lavage a breast duct to obtain a fluid sample. Hou et al clearly teaches that these elements can be used to lavage a breast duct.

The Applicants also argue that element (17) in Cecchi is not a manifold hub. The Examiner respectfully disagrees. A manifold hub is nothing more than a means of uniting various elements (in the instant case, lumens) and connecting them at a single point. Element (17) in Cecchi clearly unites various lumens (32, 33 and the outlet at 14) and connects them at a single point (denoted at 18). Therefore Cecchi teaches the use of a manifold hub.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cecchi clearly teaches the use of a means of lavaging an organ (ovary) to obtain cells (oocytes). Hou et al teach a system that is similar to Cecchi, but is used to lavage a breast duct.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BS